§ 72.7

or toxin listed in Appendix A of this part. The term also includes:

- (1) Genetically modified microorganisms or genetic elements from organisms on Appendix A of this part, shown to produce or encode for a factor associated with a disease, and
- (2) Genetically modified microorganisms or genetic elements that contain nucleic acid sequences coding for any of the toxins on Appendix A of this part, or their toxic submits.

Single geographic site means a building or complex of buildings at a single mailing address.

Transfer means:

- (1) The conveyance or movement from a point or origination to a point of destination either:
- (i) From one state or territory to another or;
- (ii) Entirely within one contiguous state or territory.
- (2) Intrafacility transfers within a registered facility located at a single geographic site are not covered by the provisions of §72.6 (d), (e), and (f) provided that:
- (i) The intended use of the agent remains consistent with that specified in the most current transfer form; and
- (ii) For each intrafacility transfer, the facility maintains records that include the name and location of the recipient; the amount of agent transferred, and the date transferred. Such records must be maintained for a period of five (5) years after the date of transfer or for five (5) years after the agents are consumed or properly disposed, whichever is longer.

Transferor means any person who transfers or seeks to transfer through any means a select agent subject to this part to any other person.

[61 FR 55197, Oct. 24, 1996]

§ 72.7 Penalties.

Individuals in violation of this part are subject to a fine of no more than \$250,000 or one year in jail, or both. Violations by organizations are subject to a fine or no more than \$500,000 per event. A false, fictitious, or fraudulent statement or representation on the Government forms required in the part for registration of facilities or for transfers of select agents is subject to a fine or imprisonment for not more

than five years, or both for an individual; and a fine for an organization.

[61 FR 55199, Oct. 24, 1996]

APPENDIX A TO PART 72—SELECT AGENTS

Viruses

- 1. Crimean-Congo haemorrhagic fever virus
- 2. Eastern Equine Encephalitis virus
- 3. Ebola viruses
- 4. Equine Morbillivirus
- 5. Lassa fever virus
- 6. Marburg virus
- 7. Rift Valley fever virus
- 8. South American Haemorrhagic fever viruses (Junin, Machupo, Sabia, Flexal, Guanarito)
- 9. Tick-borne encephalitis complex viruses
- 10. Variola major virus (Smallpox virus)
- 11. Venezuelan Equine Encephalitis virus
- 12. Viruses causing hantavirus pulmonary syndrome
- 13. Yellow fever virus

Exemptions: Vaccine strains of viral agents (Junin Virus strain candid #1, Rift Valley fever virus strain MP-12, Venezuelan Equine encephalitis virus strain TC-83, Yellow fever virus strain 17-D) are exempt.

Bacteria

- 1. Bacillus anthracis
- 2. Brucella abortus, B. melitensis, B. suis
- 3. Burkholderia (Pseudomonas) mallei
- 4. Burkholderia (Pseudomonas) pseudomallei
- 5. Clostridium botulinum 6. Francisella tularensis
- o. Francisena tuiai 7. Yersinia pestis
- Exemptions: vaccine strains as described in Title 9 CFR, 78.1 are exempt.

Rickettsiae

- 1. Coxiella burnetii
- 2. Rickettsia prowazekii
- 3. Rickettsia rickettsii

Fungi

1. Coccidioides immitis

Toxins

- 1. Abrin
- 2. Aflatoxins
- 3. Botulinum toxins
- 4. Clostridium perfringens epsilon toxin
- 5. Conotoxins
- 6. Diacetoxyscirpenol
- 7. Ricin
- 8. Saxitoxin
- 9. Shigatoxin
- 10. Staphylococcal enterotoxins
- 11. Tetrodotoxin
- 12. T-2 toxin

Exemptions: Toxins for medical use, inactivated for use as vaccines, or toxin preparations for biomedical research use at an LD_{50}

for vertebrates of more than 100 nanograms per kilogram body weight are exempt. National standard toxins required for biologic potency testing as described in 9 CFR Part 113 are exempt.

RECOMBINANT ORGANISMS/MOLECULES

- 1. Genetically modified microorganisms or genetic elements from organisms on Appendix A, shown to produce or encode for a factor associated with a disease.
- 2. Genetically modified microorganisms or genetic elements that contain nucleic acid sequences coding for any of the toxins listed in this Appendix, or their toxic subunits.

OTHER RESTRICTIONS

The deliberate transfer of a drug resistance trait to microorganisms listed in this Appendix that are not known to acquire the trait naturally is prohibited by NIH "Guidelines for Research Involving Recombinant DNA Molecules," if such acquisition could compromise the use of the drug to control these disease agents in humans or veterinary medicine.

ADDITIONAL EXEMPTIONS

- 1. Products subject to regulation under the Federal Insecticide Fungicide and Rodenticide Act (7 U.S.C. 136 et seq.) and the Toxic Substances Control Act (15 U.S.C. 2601 et seq.) are exempt.
- 2. Additional exemptions for otherwise covered strains will be considered when CDC reviews and updates the list of select agents in this Appendix. Individuals seeking an exemption should submit a request to CDC that specifies the agent or strain to be exempted and explains why such an exemption should be granted. Future exemptions will be published in the FEDERAL REGISTER for review and comment prior to inclusion in this Appendix.

[61 FR 55199, Oct. 24, 1996]

PART 75—STANDARDS FOR THE ACCREDITATION OF EDU-CATIONAL PROGRAMS FOR AND THE CREDENTIALING OF RADIOLOGIC PERSONNEL

Sec.

75.1 Background and purpose.

75.2 Definitions.

75.3 Applicability.

APPENDIX A TO PART 75—STANDARDS FOR ACCREDITATION OF EDUCATION PROGRAMS FOR RADIOGRAPHERS

APPENDIX B TO PART 75—STANDARDS FOR ACCREDITATION OF DENTAL RADIOGRAPHY TRAINING FOR DENTAL HYGIENISTS

APPENDIX C TO PART 75—STANDARDS FOR ACCREDITATION OF DENTAL RADIOGRAPHY TRAINING FOR DENTAL ASSISTANTS

APPENDIX D TO PART 75—STANDARDS FOR ACCREDITATION OF EDUCATIONAL PROGRAMS FOR NUCLEAR MEDICINE TECHNOLOGISTS

APPENDIX E TO PART 75—STANDARDS FOR ACCREDITATION OF EDUCATION PROGRAMS FOR RADIATION THERAPY TECHNOLOGISTS

APPENDIX F TO PART 75—STANDARDS FOR LICENSING RADIOGRAPHERS, NUCLEAR MEDICINE TECHNOLOGISTS, AND RADIATION THERAPY TECHNOLOGISTS

APPENDIX G TO PART 75—STANDARDS FOR LI-CENSING DENTAL HYGIENISTS AND DENTAL ASSISTANTS IN DENTAL RADIOGRAPHY

AUTHORITY: Sec. 979 of the Consumer-Patient Radiation Health and Safety Act of 1981, Pub. L. 97-35, 95 Stat. 599-600 (42 U.S.C. 10004)

SOURCE: 50 FR 50717, Dec. 11, 1985, unless otherwise noted.

§75.1 Background and purpose.

- (a) The purpose of these regulations is to implement the provisions of section 979 of the Consumer-Patient Radiation Health and Safety Act of 1981, 42 U.S.C. 10004, which requires the establishment by the Secretary of Health and Human Services of standards for the accreditation of programs for the education of certain persons who administer radiologic procedures and for the credentialing of such persons.
- (b) Section 979 requires the Secretary, after consultation with specified Federal agencies, appropriate agencies of States, and appropriate professional organizations, to promulgate by regulation the minimum standards described above. These standards distinguish between the occupations of (1) radiographer, (2) dental hygienist, (3) dental assistant, (4) nuclear medicine technologist, and (5) radiation therapy technologist. In the interest of public safety and to prevent the hazards of improper use of medical radiation identified by Congress in its determination of the need for standards, the Secretary is also authorized to prepare standards for other occupational groups utilizing ionizing and non-ionizing radiation as he/she finds appropriate. However, the standards set out below are limited to the five occupational groups listed above, utilizing ionizing radiation. Nothing in these accreditation standards is intended to discriminate against proprietary schools.